IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA,
ex rel. KEVIN GRAY **PLAINTIFF**

VS. **CIVIL ACTION: 3:15-CV-000127-MPM-JMV**

MITIAS ORTHOPAEDICS, PLLC,
and HANNA M. MITIAS, M.D. **DEFENDANTS**

ORDER

This cause comes before the court on the joint motion of defendants Mitias Orthopaedics, PLLC and Hanna M. Mitias, M.D. ("defendants") to dismiss this action, pursuant to Fed. R. Civ. P. Rule 12(b)(6). Plaintiff United States of America *ex rel* Kevin Gray has responded in opposition to the motion, and the court, having considered the memoranda and submissions of the parties, is prepared to rule.

This is a *qui tam* action brought pursuant to the False Claims Act, 31 U.S.C. § 3729 ("FCA), based on allegations that defendants submitted false claims for Medicare reimbursements based on treatments which were not actually provided. The plaintiff alleges that defendants treated patients with hyaluronic acid ("HA"), a viscosupplementation agent used to treat osteoarthritis of the knee, that was not FDA approved, and that as a result, the HA was *per se* not reimbursable by various government health care benefit programs (collectively "Medicare"). The Intervenor's Complaint also alleges that defendants falsely represented to Medicare that they were using name-brand variants of HA as opposed to compounded or generic HA, also causing the HA to be *per se* not reimbursable by Medicare.

In its brief, plaintiff describes its allegations in this regard as follows:

> As treatment for osteoarthritis of the knee, Mitias injected patients with a viscosupplementation agent ("VA") containing hyaluronan that was unlawfully manufactured and sold by a compound pharmacy. Mitias billed Medicare for these injections (for both the service and the device) under J-codes for brand-name VAs such as Synvisc or Euflexxa. Mitias gave no indication that it had injected the patients with, and was billing Medicare for, substances that were not the brand-name VA but rather a non-approved device. As a result of these claims, Medicare reimbursed Mitias for the brand-name devices.
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> These claims were false for four primary reasons. First, the claims were factually false because Mitias submitted claims for a different substance than was actually injected. Second, the claims were legally false because Mitias submitted claims for a substance that was not FDA-approved and that did not fall under a statutory exception for a non-FDA-approved product, and so was not covered by Medicare. Third, the claims were legally false because Mitias cannot provide documentation to support the medical necessity or reasonableness of the claims. And fourth, the claims were factually false because they were submitted under a qualified provider when injections were performed by non-qualified technicians.

[Response brief at 2-3 (record citations omitted)].

Defendants have presently moved to dismiss, arguing that the Intervenor's Complaint fails to assert a claim upon which relief may be granted. To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "A complaint is insufficient if it offers only labels and conclusions, or a formulaic recitation of the elements of a cause of action." *Id.* (quotation marks omitted). Even before it decided *Iqbal* and *Twombly*, the Supreme Court had long since held that courts were "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

In this case, this court considers the above dismissal standards in the context of the FCA, which imposes liability upon anyone who "knowingly presents, or causes to be presented, a false

or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.,* 355 F.3d 370, 376 (5th Cir. 2004). A "claim" includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program. 31 U.S.C. § 3729(b)(2)(A). "In determining whether liability attaches under the FCA, this court asks (1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)." *United States ex rel. Harman v. Trinity Indus. Inc.,* 872 F.3d 645, 654 (5th Cir. 2017) (citations omitted).

Defendants' motion to dismiss relies heavily upon two recent U.S. Supreme Court decisions which play an important role in this court's analysis of these matters. The first such decision is the U.S. Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar,* 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016), which considered the third FCA factor noted above, related to materiality. In doing so, the Supreme Court established a rather stringent standard of materiality, and defendants maintain that it has not been met in this case. This court will first review *Escobar*'s holding before determining whether the Intervenor's Complaint sufficiently alleges materiality as defined by the Supreme Court in that case.

The Fifth Circuit recently described *Escobar*'s holding on the materiality issue as follows:

> The Supreme Court recently elaborated on the factors that lower courts should consider in determining materiality under the FCA. In *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Court considered whether the so-called "implied false certification" theory can be a basis for FCA liability. The Court held in the affirmative, and stated that "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory or contractual requirement. In these

> circumstances, liability may attach if the omission renders those representations misleading." In other words, the Supreme Court made clear that defendants could be liable under the FCA for violating statutory or regulatory requirements, whether or not those requirements were designated in the statute or regulation as conditions of payment.
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> After their daughter's death, the relators in *Escobar* filed a qui tam suit against the defendant health provider for submitting reimbursement claims for medical services but failing to disclaim serious violations of regulations pertaining to qualifications and licensing requirements for staff performing these services. The petition alleged that the medical provider flouted regulations requiring that mental health services be performed by properly licensed clinicians (i.e., psychiatrists, social workers, or nurses). The plaintiffs' claim was based on the fact that medical benefits were paid based on requests for reimbursement for services performed by unlicensed, unqualified, and unsupervised staff—in violation of regulations that did not expressly provide that compliance was a condition of payment for these services. The defendant, Universal Health Services, however, argued that because the regulations did not make compliance with licensing and other provider qualifications conditions of payment, the violations could not be material.
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> The Supreme Court rejected Universal Health's argument, holding that "when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." In explaining its refusal to adopt a flat rule that billing for services without complying with a requirement expressly made a condition of payment is material, the Court stated: "Under Universal Health's view, misrepresenting compliance with a requirement that the Government expressly identified as a condition of payment [without regard to its importance] could expose a defendant to liability. Yet, under this theory, misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim would not."
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> *Escobar* explained some of the evidence relevant to the materiality issue: (1) "the Government's decision to expressly identify a provision as a condition of payment" and (2) "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." Moreover, (3) materiality "cannot be found where noncompliance is minor or insubstantial." The Supreme Court remanded *Escobar* to the First Circuit to reconsider materiality in light of these factors.

United States ex rel Lemon v. Nurses To Go, Inc., 924 F.3d 155, 159–60 (5th Cir. 2019).

While this court acknowledges that *Escobar* has significantly raised the probative bar in this context, it also appears to have elements which are helpful to plaintiff here. As quoted above,

the Fifth Circuit noted in *Lemon* that "defendants could be liable under the FCA for violating statutory or regulatory requirements, whether or not those requirements were designated in the statute or regulation as conditions of payment." *Id.* This court regards this portion of *Escobar* as helpful for plaintiff in this case, since, as discussed below, the defendants contend that the Government did not make the rules regarding reimbursement for generic or compound HA products sufficiently clear in this case. Nevertheless, it is certainly true that other aspects of *Escobar* are helpful to defendants, such as the Supreme Court's holding that:

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. * * *
>
> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Escobar, 136 S. Ct. at 2003 (citation omitted).

While this court acknowledges that *Escobar* sets the materiality bar high, it concludes that the Intervenor's Complaint includes extensive allegations which, if supported by proof in discovery, might lead a reasonable jury to conclude that defendants acted with the requisite degree of knowledge of wrongdoing, even under this stringent standard. This court will presently discuss allegations in the complaint which lead it to this conclusion. The Intervenor's Complaint initially notes that Relator Kevin Gray, who worked for a "name-brand" manufacturer of HA, became

aware of questions regarding the legality of false claims in this context based on a decision from another federal court. Specifically, the Intervenor's Complaint alleges that:

> 41. Relator Kevin Gray is a Regional Sales Specialist for Ferring Pharmaceuticals. As such, part of his job is to market Euflexxa® and to educate physician practices on the benefits of his company's product, and why it should be their practice's choice for viscosupplementation.
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> 42. Because part of his job involves persuading physicians not to use compounded, counterfeit, or other hyaluronic acid products for viscosupplementation that are not FDA-approved, Relator became aware of the case of U.S. ex rel. Estey in the Eastern District of Tennessee, Civil Action No. 3:12-cv-00085. In that case, the Department of Justice intervened and settled a qui tam case alleging that two physician practices were billing for Synvisc but actually injecting hyaluronic acid containing products purporting to be Synvisc, but not FDA-approved purchased from outside the U.S. at deep discount.
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> 43. Relator Gray used this case to explain to physician's groups the dangers of using viscosupplementation products that are not FDA-approved.
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> 44. On or about April 12, 2015, Ferring received a call indicating that Mitias was seeking a quote for purchasing Euflexxa. No local representative was assigned to the area, and so Relator Gray agreed to contact Mitias Orthopaedics to make a presentation regarding the product and to provide information based on the needs of the practice.

[Intervenor's Complaint at 9].

The Intervenor's Complaint describes how, after traveling to defendants' medical office, Gray developed concerns regarding the apparent willingness of Dr. Mitias and his staff to risk patient health and safety by using sub-standard HA products. Specifically, the Intervenor's Complaint alleges that:

> 45. On or about April 14, 2015, Relator Gray conducted a phone call with Brad Robbins, a physician's assistant at Mitias.
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> 46. During this call, Relator asked what product the practice was currently using. To his surprise, he was told casually by Robbins that Mitias did not purchase any of the viscosupplementation agents on the market. Instead, it was Mitias' practice to use hyaluronic acid products produced by and purchased from a pharmacy.

47. Robbins told Relator that Mitias was reaching out to all the manufacturers/marketers of FDA-approved "branded" viscosupplementation because they were no longer able to use the product made at the compounding pharmacy.

48. A lunch meeting was scheduled for the following week to cover Relator's product information in more detail.

49. On or about April 22, 2015, Relator Gray conducted a sales meeting with Mitias Orthopaedics in New Albany, MS.

50. At the beginning of the lunch meeting, Relator Gray met with several of the clinical staff, including Dr. Keith Box and physician assistant Brad Page. Relator Gray learned that the pharmacy provided Mitias with three different products: a single injection, a three-injection regimen, and a five-injection regimen.

51. Relator Gray also learned that virtually the entire staff, including the Radiology Technicians ("RTs"), were performing viscosupplementation agent injections.

52. In fact, the majority of the viscosupplementation agent injections in the practice were performed by one unqualified RT.

53. Relator Gray was further informed that ultrasound guidance was used on every injection, whether it was needed or not, because Mitias was able to bill more for injections with ultrasound.

54. Mitias requires that bi-lateral patients have the procedures on different days, thus allowing Mitias to bill twice to achieve the maximum profit. In other words, instead of performing both injections and billing CPT Code 20610 with the -50 modifier, so that Federal Health Plans pay 150%, Mitias schedules separate appointments so that it can bill CPT Code 20610 twice and get paid 100% twice.

55. The clinical staff told Relator Gray that the only reason the practice was taking quotes on "real" viscosupplementation products was because the compounding pharmacy they were using was based in Arkansas and changing regulations were going to prohibit shipment of the product across state lines.

56. Non-FDA approved Class III medical devices are not subject to FDA control, regulations, and protections. With a product produced at a pharmacy without FDA-approval and oversight, it is often difficult to know what is actually being purchased, be it physically and chemically-similar Euflexxa, Synvisc-One, Supartz, some other substance entirely, or even a placebo. These products are subject to tampering, dilution, modification, spoliation, and other changes during manufacture which can make them harmful to patients.

[Intervenor's Complaint at 10].

The Intervenor's Complaint specifically cites one instance of actual patient harm resulting from the use of sub-standard HA products[1]:

> 57. Underscoring this potential for harm, Relator Gray was further told that Mitias had once received a "bad batch" of hyaluronic acid product from a former compounding pharmacy. As a result of this bad batch, many patients had severe acute inflammatory reactions at the injection site, often requiring additional medical attention (e.g., draining the excess fluid from the knee, corticosteroid injections to "calm" the inflammation and pain, etc.). These became so common that Mitias decided they needed to change products. However, rather than starting to purchase FDA-approved viscosupplementation products, Mitias simply switched pharmacies and continued purchasing devices not approved by FDA.

[Intervenor's Complaint at 10-11].

The Intervenor's Complaint clearly alleges that increasing profits was at the forefront of defendants' considerations in deciding which HA products to use and how to bill Medicare for them. Specifically, the Intervenor's Complaint alleges that:

> 58. Therefore, upon information and belief and since at least 2008 through 2015, Mitias has purchased non-FDA approved products from one of two pharmacies and Mitias provided it to patients under the guise that it was Synvisc or another FDA-approved hyaluronic acid product. The purchase price for these non-FDA approved hyaluronic acid products was significantly lower than would be available for FDA-approved hyaluronic acid products.
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> 59. At the sales meeting, Relator Gray, Mr. Page, Dr. Box, and the clinical staff were joined by Brad Robbins (PA) and Ben Morris (Management). Morris was openly hostile, stating that the viscosupplementation agent manufacturers (like Ferring Pharmaceuticals) had caused their compounding pharmacy to not be legally able to ship their products to Mitias by lobbying for a change in the laws regarding such pharmacies.
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> 60. In response, Relator informed Morris that it has always been fraudulent to use a compounding pharmacy to ship bulk quantities of viscosupplementation products that are not FDA-approved.

[1] Defendants deny that this incident actually occurred, although they then proceed to assert that, even if it did occur, "that type of issue happens throughout the pharmaceutical industry." [Motion to dismiss at 18]. Ultimately, this court does not regard the issue of patient harm as being of crucial relevance in this case, since it does not appear to impact the elements of the FCA claim in this case. Nevertheless, this court includes these allegations in this order since it helps to highlight the importance of some of the issues at stake in this case.

61. Relator Gray asked how Mitias could possibly bill for such product, and was told that the practice generally billed for Synvisc-One, unless the patient or their insurance company had a different preference. In cases where some specific FDA-approved product was requested, Mitias billed for whatever the patient or insurance company indicated should be used, despite using different products that were not FDA-approved.

62. In other words, if Patient A wanted Supartz (which is FDA-approved for 5 injections), he would be administered a five-injection of a hyaluronic acid product produced at a pharmacy and not FDA-approved and billed for Supartz; however, if Patient B's insurance company wanted Euflexxa (which is FDA-approved for 3 injections), she would be administered three injections of a hyaluronic acid product produced at a pharmacy, but billed for Euflexxa. And if Patient C expressed no preference and had no insurance requirement, he would be billed for Synvisc-One as the default—but again, would receive the single dose hyaluronic acid product produced at a pharmacy and not FDA-approved.

63. Although the clinical staff informed Relator that they were told these injections were in fact different from one another, due to their different molecular weights, it is unclear whether the substance administered five times was any different than the three injection or single injection substance. It is believed the molecular weights had not been tested and controlled as they would be under proper manufacturing conditions.

64. Morris was very blunt that Mitias' decision concerning which viscosupplementation agents to purchase would be determined by how much profit Mitias could make from the injections. Upon seeing the tiered price structure for Euflexxa, Morris expressed shock at how much less profitable using Euflexxa would be for their practice. Relator Gray was told that the clinical efficacy and safety information that was presented would simply not be taken into consideration.

65. The group was then joined by Dr. Mitias himself, who complained that Mitias would no longer be making a large profit from viscosupplementation injections now that they were being forced to buy FDA-approved hyaluronic acid products. Dr. Mitias again confronted Relator Gray with the assertion that it was the fault of Ferring and the other manufacturers that they were being forced to change from such a profitable model. Dr. Mitias made reference to the "actual cost" of manufacturing viscosupplementation and that the practice was simply avoiding the industry mark-up.

66. In response, Relator Gray explained the financial investments related to the large clinical trials, the FDA approval process, and the strict quality control measures that are needed to ensure patient safety were the reasons for the extra cost, not "mark-up."

67. Dr. Mitias continued to be aggressive and hostile. He informed Relator that since CMS lists the HCPCS code for viscosupplementation agents with a portion

> that reads "or derivative," CMS permits Mitias to use any viscosupplementation agent and bill for any of the J-codes associated with the FDA-approved "branded products."
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> 68. Dr. Mitias stated that Mitias received an approval from Medicare to bill this way, and he produced a letter, on his phone, as proof.
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> 69. Relator Gray reviewed the letter on Dr. Mitias' phone during the meeting. The letter, not from Medicare, appearing to be from the American Hospital Association's billing/coding department, allows for billing of Supartz or Hyalgan under the same J-code. However, this code (J7321) is the only J-code that has more than one product associated with it. This code does not cover, that is does not describe, non-FDA-approved devices.

[Intervenor's Complaint at 12-14].

These and other allegations in the Intervenor's Complaint lead this court to conclude that plaintiff sufficiently alleges that the materiality requirement is met in this case, even under the heightened standard set forth in *Escobar*. In the court's view, the Intervenor Complaint's allegation that Dr. Mitias represented to Gray that he had obtained Medicare's permission to bill using the codes for name-brand HAs, when his offered proof did not support this representation, raises questions whether he knew that Medicare would not actually support his billing practices. This court's conclusion in this regard is strengthened by the fact that the Intervenor's Complaint alleges, and defendants do not appear to dispute, that the they billed Medicare using the codes for specific brand-name HAs produced by manufacturers, when they were actually using "compound" HA products developed by pharmacies. For example, the Intervenor's Complaint alleges, with regard to the brand-name Euflexxa, that:

> Euflexxa® is billed under HCPCS code J7323. The description specifically states: "Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose."

[Intervenor's Complaint at 7].

While the Intervenor's Complaint notes Dr. Mitias' position that the words "or derivative" in the billing code allowed him to use the codes for brand name HA products while actually

administering pharmacy-prepared compounded products to patients, this court regards the issue of his state of mind in light of this language (including his level of scienter) as a jury issue. In so stating, this court observes that defendants have submitted no arguments that they actually sought a clarification from Medicare on this issue, and a jury may look with skepticism upon the argument that these two words in the billing code allowed Dr. Mitias to greatly increase his profits for years by using cheap pharmacy-prepared products and billing for them under codes assigned to more expensive brand-name products, without at least seeking clarification from Medicare. A jury may be even more skeptical in this regard if Gray testifies consistent with the allegations above regarding the statements Dr. Mitias made to him regarding his actions and his profit-based motivation for them.

In their response, defendants vigorously deny that Dr. Mitias made many of the statements attributed to him, but it is well established that, at the Rule 12 stage of proceedings, it is required to accept them as true. This court would certainly not expect the United States to knowingly include false allegations in its complaint, and its basic narrative, whereby defendants allegedly sought to cut corners and submit false information in the interests of increasing their profits, has a certain plausibility to it under *Iqbal/Thombly*. This court presumes that the Relator will testify consistent with the allegations above in his deposition. If that proves to be the case, then it is unclear to this court how it might, consistent with the deferential summary judgment standard, simply assume that he is lying on these issues. In finding likely jury issues in this context, this court notes that the Fifth Circuit's decision in *Lemon* makes it clear that *Escobar* is not a panacea for defendants in FCA cases, since the Fifth Circuit reversed the district court's Rule 12 dismissal in that case. *United States ex rel Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 159–60 (5th Cir. 2019)(reversing dismissal under the "demanding" yet "holistic" approach set forth in *Escobar*).

In their brief, defendants write that the Intervenor Complaint's "allegations fail to sufficiently plead a material false claim because they fail to identify a properly enacted substantive legal standard that the defendants violated, i.e. something that told the defendants Medicare would not knowingly pay for the use of compound or generic HA at the time the claims were submitted." [Motion to dismiss at 8]. In the court's view, defendants' argument that they had no way of knowing that Medicare would not knowingly pay for compound or generic HA when billed under codes for brand-name HA products may strike a jury as being rather disingenuous, particularly since Dr. Mitias apparently sought no clarification of these matters from Medicare. True enough, defendants have an argument that the words "or derivative" in the billing codes allowed Dr. Mitias to bill for pharmacy-prepared products under the codes for name-brand products, but a jury may regard that as a very convenient and self-serving argument, under the circumstances of this case.

This court admits to a considerable degree of skepticism regarding Dr. Mitias' position in this case, based partly upon the issue of reimbursement rates. The Intervenor's Complaint alleges, and an internet search confirms, that prior CMS rulemaking has tied reimbursement rates for particular drugs to the cost of obtaining them. For example, one online article notes that:

> In 2016, the Centers for Medicare & Medicaid Services (CMS) finalized regulations that changed Medicaid payment for ingredient cost from an "estimated acquisition cost" (EAC) to an "actual acquisition cost" (AAC). CMS defines AAC as the state Medicaid agency's determination of pharmacy providers' actual prices paid to acquire drug products marketed or sold by a specific manufacturer.

See https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs.

This court presumes that, as a physician, Dr. Mitias was aware that Medicare generally ties reimbursement rates to the costs of the drugs in question. That being the case, this court wonders how Dr. Mitias could have sincerely believed that, by including the words " or derivative" in the

billing code for brand-name HAs, Medicare was expressing a willingness to pay the same reimbursement rate for compounded HAs obtained from a pharmacy at a comparatively low cost as it would for the actual brand-name HAs, obtained at a much higher cost. This seems to fly in the face of Medicare's normal reimbursement rate practices, and the notion that the Government would have been content to allow Dr. Mitias to pocket the difference in this regard frankly strikes this court as far-fetched. Indeed, this court wonders why, from a purely financial perspective, a physician would *ever* choose to use name-brand HAs if he could lawfully do what Dr. Mitias did in this case. This court therefore doubts that Dr. Mitias sincerely believed that the words "or derivative" in the billing codes gave him a legal right to do what he did in this case.

This court notes that defendants do appear to cast considerable doubt upon one of plaintiff's claims in this case, which is based upon an assertion that non-FDA approved HAs were *per se* not reimbursable by Medicare.[2] However, defendants' arguments on this issue appear to cast further doubt upon Dr. Mitias' alleged actions that most concern this court, namely his decision to bill for non-FDA approved HAs using the codes for brand-name HAs. As to this issue, defendants argue in their brief that:

> The plaintiff alleges that the use of non-name brand HA was *per se* not reimbursable by Medicare. This attempt to meet the "rigorous" and "demanding" materiality burden is thwarted by the same HCPCS manual the plaintiff relies on to support its allegations of fraud. HCPCS code J3490, defined as a code to be used for "unclassified drugs" specifically lists "hyaluronic acid" as one of the injectable drug substances that are reimbursable by using that code. * * * Code J3490, which has been in effect since January 1, 1997, does not list any of the name brand HA variants that the plaintiff wrongly claims are the only variants of HA that are reimbursable by Medicare. The inclusion of a non-specific HA as a reimbursable "unclassified drug" in every HCPCS manual during the relevant time frame inflicts

[2] If plaintiff continues to pursue this claim, then this court will give serious consideration to dismissing it at the directed verdict stage of trial. Given the complexities of these issues, however, this court is inclined to wait until that stage to make a final ruling on them, since it appears that a trial will be required regardless on the issue of Dr. Mitias' actions in billing for non-FDA approved HAs using the codes for brand-name, FDA-approved HAs.

> a fatal blow on the plaintiff's factually unsupported and conclusory claim that Medicare would only pay for name brand, FDA-approved HA. Clearly, whether the HA used by a provider was an FDA approved "name brand" device or a compounded or generic version was not material to whether Medicare would reimburse a provider for its use.

[Brief at 14-15 (citations omitted)].

Defendants thus argue that there is, in fact, a Medicare billing code for generic HAs, and, if that is the case,[3] then it would tend to cast doubt upon plaintiff's argument that only brand-name HAs were reimbursable. However, this same fact, if assumed to be true, raises the question of why Dr. Mitias used the code for brand-name HAs if there was a code for generic HA which he could have used. This court can thus discern serious tension between defendants' arguments on the various claims in this case, and their arguments on what appears to be plaintiff's weakest claim appears to harm their position with regard to its strongest claim. In the court's view, Dr. Mitias' alleged actions in using the codes for brand-name HAs which he was not actually administering to patients is so clearly suggestive of a knowing dishonesty that it allows plaintiff to meet even the stringent scienter/materiality requirements set forth in *Escobar*.

In the court's view, the strength of plaintiff's claim regarding Dr. Mitias' alleged billing practices lies largely in the fact that their wrongfulness seems so obvious. Once again, the complaint alleges that:

> 61. Relator Gray asked how Mitias could possibly bill for such product, and was told that the practice generally billed for Synvisc-One, unless the patient or their insurance company had a different preference. In cases where some specific FDA-approved product was requested, Mitias billed for whatever the patient or insurance company indicated should be used, despite using different products that were not FDA-approved.
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> 62. In other words, if Patient A wanted Supartz (which is FDA-approved for 5 injections), he would be administered a five-injection of a hyaluronic acid product

[3] It seems clear to this court that resolving this issue falls well outside of the scope of a Rule 12 motion based on the pleadings.

> produced at a pharmacy and not FDA-approved and billed for Supartz; however, if Patient B's insurance company wanted Euflexxa (which is FDA-approved for 3 injections), she would be administered three injections of a hyaluronic acid product produced at a pharmacy, but billed for Euflexxa. And if Patient C expressed no preference and had no insurance requirement, he would be billed for Synvisc-One as the default—but again, would receive the single dose hyaluronic acid product produced at a pharmacy and not FDA-approved.

[*Id.*] This court is required to accept these allegations as true at this juncture, and, while defendants deny that Dr. Mitias made the incriminating statements attributed to him, this court's understanding is that plaintiff has documentary billing evidence which supports its claims. Moreover, defendants argue that they "believed they could utilize the relevant billing codes because the description in the codes included 'derivatives' of HA," [brief at 2] and it thus appears to be undisputed that Dr. Mitias did, in fact, use the codes for name-brand drugs he was not actually administering to patients.

In light of the foregoing, this court concludes that the Intervenor's Complaint sufficiently alleges materially false claims, even under the stringent standard set forth in *Escobar*. This court now turns its attention to the second U.S. Supreme Court decision which casts a lengthy shadow over this case, namely its 2019 decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). In *Allina*, the Supreme Court was called upon to interpret a Medicare Act provision, 42 U.S.C. § 1395hh(a)(2), which provides that:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

The Supreme Court interpreted this statute as meaning that an agency change in the interpretation of a rule governing Medicare payment to hospitals had to go through notice and comment to be implemented. *Allina*, 139 S. Ct. at 1813–15. *Allina* involved a new Medicare payment formula

posted by CMS on its website that had the effect of substantially reducing payments to hospitals that served low-income patients. *Allina,* 139 S. Ct. at 1808. The Supreme Court invalidated the rule, holding that it was a "substantive legal standard" that could not go into effect without the notice and comment period required by § 1395hh(a)(2). *Allina,* 139 S. Ct. at 1811–14, 1817.

Allina was not a FCA case, but it nevertheless casts doubt upon one method by which plaintiff seeks to prove materiality in this case, namely a so-called "Local Coverage Determination" or "LCD." The question of whether an LCD may serve as a basis for a finding of materiality is significant in this case, since plaintiff appears to concede that there was no actual Medicare statute which prohibited the use of non-brand name HAs such as the ones at issue here. In their brief, defendants chide plaintiff for its proof in this context, writing that it "did not identify any 'laws, regulations or rules' that established a prohibition on payment for non-name brand HA used in the course of treatment for osteoarthritis of the knee" and that it instead "places all of its proverbial eggs into the basket of a Local Coverage Determination ("LCD") that was issued by a government contractor." [Reply brief at 2]. Defendant argues that "*Allina* . . . makes it clear that sub-regulatory guidance materials like the ones relied upon by the plaintiff, that have not been implemented through the Medicare Act's statutorily required notice and comment rulemaking provisions cannot establish the basis on which an enforcement action is premised." [Reply brief at 1].

Plaintiff does not deny that it is relying partially upon an LCD to establish the illegality of the billing practice at issue in this case, but it cites the recent decision of *United States ex rel., Alt v. Anesthesia Services Assoc. PLLC.*, 2019 WL 7372510 (M.D. Tenn. 2019), for the proposition that *Allina* does not bar the use of LCDs in support of an FCA claim. In rejecting the motion to dismiss filed in *Alt*, the District Court for the Middle District of Tennessee wrote that:

> *Allina* did not concern LCDs and certainly did not establish that all LCDs set forth substantive legal standards, nor did it address the question of whether a false certification of compliance with an LCD may form the basis of a claim under the FCA. Moreover, neither party here has actually briefed the question of whether the particular LCDs at issue should be considered to establish substantive legal standards, nor have the parties addressed the question of whether *Allina* has any application at all in the context of a case asserting FCA claims, as opposed to a case specifically contesting the denial of Medicare claims for reimbursement. At this juncture, the court does not read *Allina* to support dismissal of any claims asserted in this case.

Alt, 2019 WL 7372510 at *15. In response, defendants criticize the result in *Alt* as failing to "fully appreciate the breadth of the decision in *Allina*," and they argue that the Supreme Court's opinion is broader than the district court indicated. [Reply brief at 4-5].

For its part, this court acknowledges that defendants have substantial arguments on this issue, and it does not rule out the possibility that it will eventually agree with their interpretation of *Allina* in this case. This court recognizes that there is language in *Allina* which would seem to cast doubt upon using LCDs which did not go through the formal notice-and-comment rulemaking as being the basis for an "enforcement action," such as an attempt by the Government to recover Medicare amounts paid. At the same time, this court believes that there are good reasons to agree with the *Alt* district court's reluctance to extend *Allina* to the FCA context, and this is particularly true in cases where, as here, the defendant is essentially seeking to essentially apply it *retroactively* to FCA cases. In so stating, it is far from clear to this court that an FCA action is an "enforcement action" within the meaning of defendants' brief,

This court notes that, in their brief, defendants make reference to a 2019 opinion letter by a government lawyer which casts doubt upon such "enforcement actions" post-*Allina*. [Reply brief at 7, citing Exhibit A]. However, it seems unlikely to this court that an FCA claim would be considered an "enforcement action" within the meaning of the letter in question, which characterizes such actions as including "overpayment collections based on audits, but generally do

not include routine claims and cost report procedures." *See* opinion letter at 1, footnote 1. In so stating, this court emphasizes that FCA claims are based on false statements made with a rather high degree of scienter under *Escobar*, and not mere underpayments. As discussed in greater detail below, this court believes that if Dr. Mitias is found to have to have knowingly made false statements regarding the treatment provided to patients in seeking Medicare reimbursement, then an FCA action based on that conduct would be enforcing the interest against knowingly false claims, and not a simple collection action such as the type referenced in the letter in question. At any rate, the opinion of a single government lawyer is hardly conclusive in this context, even if it is presumed to apply to FCA actions.

Supreme Court precedent interpreting the FCA heightens this court's doubts regarding whether FCA actions would necessarily be subject to *Allina*. As discussed previously, the Fifth Circuit noted in *Lemon* that, under *Escobar*'s holding, "defendants could be liable under the FCA for violating statutory or regulatory requirements, whether or not those requirements were designated in the statute or regulation as conditions of payment." *Lemon*, 924 at 159–60. The defendant in *Escobar* argued that because the regulations did not make compliance with licensing and other provider qualifications conditions of payment, the violations could not be material. The Supreme Court rejected that argument. *Id.* at 160. Once again, the Fifth Circuit noted in *Lemon* that *Escobar* instead adopted a materiality standard which, while stringent, focuses largely upon the defendant's knowledge and understanding of the Government's payment practices, whether they had been formally identified as a condition of payment or not. Specifically, the Fifth Circuit wrote that:

> *Escobar* explained some of the evidence relevant to the materiality issue: (1) "the Government's decision to expressly identify a provision as a condition of payment" and (2) "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the

> particular statutory, regulatory, or contractual requirement." Moreover, (3) materiality "cannot be found where noncompliance is minor or insubstantial." The Supreme Court remanded *Escobar* to the First Circuit to reconsider materiality in light of these factors.

Id.

With this standard in mind, it strikes this court as being a considerable leap to apply the Supreme Court's 2019 decision in *Allina* not only to FCA actions (which involve their own unique standards), but essentially *retroactively* to FCA actions arising out of claims which were made long before *Allina* was decided. In the court's view, *Escobar*'s reference to "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" seems to be written in terms of government payment practices *at the time* and its reference to mere "contractual" requirements suggests that the legal basis for such practices may be broad indeed. This makes sense, since the FCA is concerned – as its name suggests - with the making of false claims, and this court can discern no good reason why Congress would not want to discourage the providing of knowingly false information which is material to the Government's payment practices at a particular time. This is true even if, years later, a Supreme Court decision casts doubt upon the legal basis for at least some of those payment practices.

If the evidence in this case suggests that, between 2011 to 2015, defendants knowingly mis-stated that they were administering specific DEA-approved drugs to patients, and that these mis-representations were material based upon payment approval standards existing at the time, then it is unclear to this court why the Supreme Court's decision in *Allina* should, in effective, serve as a retroactive get-out-of jail free card for them in this case. As discussed previously, the Intervenor's Complaint alleges that defendants administered non-approved HA compounds prepared by a pharmacy, while using the payment codes for specific drugs which, they were aware,

were not actually being administered to patients. Under this factual scenario, it is unclear to this court why the Supreme Court's 2019 decision in *Allina* would assist defendants here, even if it were to assume that the decision has since cast doubt upon the use of informal LCDs as the basis for Medicare billing enforcement actions relating to HAs.

That brings this court to an important point, namely that defendants' *Allina* arguments seem focused on the weaker of plaintiff's claims, namely that non-brand name HAs were *per se* not reimbursable by Medicare. As quoted previously, defendants argue that plaintiff "did not identify any 'laws, regulations or rules' that established a prohibition on payment for non-name brand HA used in the course of treatment for osteoarthritis of the knee," *id.*, and this argument clearly seems focused on this weaker claim. As discussed previously, this court has serious questions about this claim even aside from *Allina*, and it believes that plaintiff should consider dropping it. If plaintiff does not do so, then this court is presently inclined to dismiss it at the directed verdict stage of trial, barring truly persuasive evidence in support of it.

Regardless of how this court eventually rules on plaintiff's weaker claim, it can not discern a valid argument that *Allina* has an impact upon its stronger claim, which is based upon a simple assertion that, in seeking Medicare reimbursements, defendants made false representations regarding the treatment which they provided to patients. Moreover, defendants allegedly made these mis-representations under circumstances which might lead a jury to conclude that they involved an attempt to deceive Medicare in order to increase their own profits. This court questions whether an LCD is actually needed to advise doctors that they should not engage in practices of this nature, without at least obtaining a confirmation from Medicare that such was allowed.

This court has reviewed the language of the LCD in this case, and it appears to be rather vaguely worded and less applicable to the conduct alleged in the case than the simple fact that Medicare had chosen to assign billing codes to specific FDA name-brand products, which suggests that those codes should only be used when the products in question are actually administered to patients. As noted previously, defendants contend that there is, in fact, a code for generic HA, and, if that is assumed to be the case, then this seems, once again, to cast even further doubt upon their alleged actions in this case. Even assuming that *Allina* might, in fact, apply retroactively to an LCD issued in an FCA case under an appropriate set of facts, this court questions whether a formal rule-making process is needed for Medicare to essentially tell doctors that "you should only bill using the codes for the products you are actually administering to patients." This strikes this court as being less the proper subject of formal rule-making than a ministerial billing matter from Medicare's perspective and a question of simple honesty and common sense from the doctor's perspective.

In their brief, defendants attempt to frame the issue in this case as their ability to use generic or "compound" HAs,[4] but this is not a case where they acknowledged administering such generic HAs to patients and sought a ruling from Medicare regarding their reimbursement. Rather, this is a case where defendants are alleged to have falsely claimed, in seeking Medicare reimbursements, that they administered specific name-brand HAs, while they actually administered generic HAs obtained at much lower cost and pocketed the higher reimbursement rates applicable to name-brand HAs. Under these circumstances, it strikes this court as rather disingenuous for defendants to seek recourse in *Allina* and argue that the question of reimbursements for generic HAs should

[4] Specifically, defendant writes in his reply brief that "the plaintiff also did not identify any regulations or rules that address its theory of liability regarding eligibility for reimbursement of non-name brand or compounded HA by Medicare." [Reply brief at 2].

have been the subject of formal rule-making process. In the court's view, providing false information to Medicare regarding the nature of the treatment provided to patients is clearly and obviously wrong under any rule-making scheme.

It seems likely that, if a rule-making process had occurred on the issue of generic HAs, and if reimbursement had been approved, then it would have been at a considerably lower reimbursement rate than for name-brand HAs. Indeed, as discussed previously, tying reimbursement rates to the cost of drugs seems to be standard Medicare practice. This practice certainly strikes this court as logical, and plaintiff alleges that defendants' alleged actions were designed to bypass this process, for their own financial benefit. As noted previously, the Intervenor's Complaint alleges that Dr. Mitias personally complained about his lower profits in light of being forced to buy FDA-approved HA products:

> The group was then joined by Dr. Mitias himself, who complained that Mitias would no longer be making a large profit from viscosupplementation injections now that they were being forced to buy FDA-approved hyaluronic acid products. Dr. Mitias again confronted Relator Gray with the assertion that it was the fault of Ferring and the other manufacturers that they were being forced to change from such a profitable model. Dr. Mitias made reference to the "actual cost" of manufacturing viscosupplementation and that the practice was simply avoiding the industry mark-up.

[Id. at 13]. In light of allegations such as these, this court doubts that *Allina* has any impact upon plaintiff's stronger claim, which does not implicate potential rule-making issues as much as alleged mis-representations on the part of defendants regarding the treatment provided to patients. Nevertheless, this court will reserve a final judgment on *Allina*'s applicability until a later date, most likely at the directed verdict stage of trial.

It seems highly likely that a jury trial will, in fact, be required in this case, but in the meantime, this court suggests that each side take a candid look at the strengths and weaknesses of their case and consider an amicable resolution of this action during the settlement conference

presently set for February 21, 2021. While this court believes that plaintiff makes strong factual allegations in this case, it also concludes, for the reasons previously stated, that there are significant issues raised by *Allina* in this case. Moreover, defendants do appear to at least have a jury argument that the language of the billing codes provided a legal basis for their actions in this case, and a jury may conclude that the Government should have made its billing practices in this context clearer. This court therefore recommends that both sides take stock of the difficult issues in this case and proceed accordingly at the settlement conference. This court sees no basis for dismissing this action, however, and defendants' motion will therefore be denied.

In light of the foregoing, it is hereby ordered that defendants' motion to dismiss is **DENIED**.

This, the 11th day of January, 2021.

/s/ Michael P. Mills
UNITED STATES DISTRICT JUDGE
NORTHERN DISTRICT OF MISSISSIPPI